

BMJ Open Quality **Strengthening value-based medication management in a free clinic for the uninsured: Quality interventions aimed at reducing costs and enhancing adherence**

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ABSTRACT

Skyrocketing costs of prescription medications in the USA pose a significant threat to the financial viability of safety net clinics that opt to supply medications at low to no out-of-pocket costs to patients. At the East Harlem Health Outreach Partnership clinic of the Icahn School of Medicine at Mount Sinai, a physician-directed student-run comprehensive primary care clinic for uninsured adults of East Harlem, expenditures on pharmaceuticals represent nearly two-thirds of annual costs. The practice of minimising costs while maintaining quality, referred to as *high-value* care, represents a critical cost-saving opportunity for safety net clinics as well as for more economical healthcare in general. In this paper, we discuss a series of quality improvement initiatives aimed at reducing pharmacy-related expenditures through two distinct yet related mechanisms: (A) promoting value-conscious prescribing by providers and (B) improving patient adherence to medication regimens. Interventions aimed at promoting value-conscious prescribing behaviour included blacklisting a costly medication on our clinic's formulary and adding a decision tree in our mobile clinician reference application to promote value-conscious prescribing. Interventions targeted to improving patient adherence involved an automated text messaging system with English and Spanish refill reminders to encourage timely pick-up of medication refills. As a result of these processes, the free clinic experienced a 7.3%, or \$3768, reduction in annual pharmacy costs. Additionally, medication adherence in patients with diabetes on oral antihyperglycaemic medications increased from 55% to 67%. Simultaneous patient-based and provider-based interventions may be broadly applicable to addressing rising pharmacy costs in healthcare across the USA.

PROBLEM

Rising costs of medications in the USA pose significant risk to the health of patients who suffer from significant economic hardship and lack prescription drug coverage.¹ Those who fare the worst are often persons with chronic illnesses who depend on continual

supply of medications to control disease. Some safety net clinics attempt to mitigate this financial barrier by supplying medications to patients at limited out-of-pocket cost. Ample evidence suggests that prescription drug coverage for the uninsured improves health outcomes significantly.² While increasing pharmacy-related costs undoubtedly affect all modes of healthcare delivery, the limited budgets of small, donation-sustained safety net clinics are particularly vulnerable. In 2015 alone, prescription drugs cost the American healthcare system over \$300 billion, representing an 8.5% increase from expenditures in the previous year.³ Drug-related costs can further result in long-term financial harm to patients, which negatively impact their care through non-adherence to medications and inability to pay for other essential healthcare services.⁴ Safety net clinics that opt to supply medications through their own resources have a fiscal responsibility to ensure high rates of adherence and reduce overprescribing of unnecessary or expensive alternatives.

Founded in 2004, the East Harlem Health Outreach Partnership (EHHOP) clinic of the Icahn School of Medicine at Mount Sinai is a physician-directed student-run primary care clinic for uninsured adults of East Harlem, a neighbourhood that ranks high among New York City's sickest and poorest.⁵ The clinic provides primary care and limited cohabiting specialty services such as mental health, ophthalmology, gynaecology and cardiology on Saturdays. On an average clinical day, 63% of patients are solely Spanish speaking.⁶ As a volunteer-run clinic supported through philanthropy and grants, EHHOP currently provides all patient services, including prescription



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medications and supplies, to over 222 patients annually, free of charge.

Pharmacy-related costs constitute the majority of expenditures at EHHOP and are climbing. In 2013, EHHOP pharmacy expenditures totalled nearly \$27 000; in 2014, this rose by nearly 100% to just over \$51 000 despite a nominal change in the numbers of patients served. Review of the 2015 cost data revealed that pharmacy-related costs accounted for 63% (\$51 579) of its total (\$82 502) expenditures.⁵ The increase in cost for various medications was a significant, but not exclusive, contributor to the doubling of expenditures. On reviewing prescription practices, we found that both a lack of value-conscious prescribing by our providers and low medication adherence by our patients substantially contributed to high pharmacy expenditures. This revealed several opportunities for our clinic to evaluate our clinicians' prescribing habits as a means to mitigate the high-cost impact of pharmacotherapies.

Additionally, a closer review of medication expenses revealed that 32% of the pharmacy budget was spent on oral diabetic medications. Many patients with diabetes are prescribed multiple oral antihyperglycaemic medications after clinicians determine that escalating monotherapy is insufficient to manage this disease; clinicians, however, often miss an opportunity to address adherence as a primary reason for insufficient control.⁷ The WHO has estimated that adherence to medications for chronic illnesses such as diabetes averages about 50% in developed countries. Addressing medication adherence in patients with diabetes and thus preventing the addition of multiple medications provides a valuable opportunity to improve patient outcomes and optimise value and reduce pharmacy expenditures for the clinic overall.

BACKGROUND

The cost of prescription medications in American healthcare has increased drastically, with an 8.5% increase in US pharmacy spending in 2015 compared with 2014.³ Prescription drugs accounted for 9.8%, or approximately \$300 billion, of total national health expenditures in 2014.³ The importance of cost-conscious prescribing in patient care has never been more relevant.

Value-conscious prescribing, in which physicians weigh both the cost and efficacy of medications when making prescription decisions, has increasingly been linked to better patient outcomes.⁴ Despite the growing need for providers to consider the impact of prescribing costly medications, many physicians feel underprepared to make cost-related medication decisions. Formal medical education currently ignores drug cost considerations in curricula.⁸ As a result, there has been a growing interest in the development of interventions aimed at educating physicians, particularly those in general internal medicine who manage patients with

multiple chronic conditions, on the costs of commonly prescribed medicines.^{8,9}

It is further estimated that \$100–\$300 billion of annual healthcare spending can be attributed to medication non-adherence.¹⁰ Specifically relating to patients with diabetes, multiple review studies have shed light on the direct association between low adherence and increased healthcare costs.^{11,12} It is estimated that patients with poor control of their diabetes are three to four times more expensive to treat than those with good control—with adherence to medication being a central determinant of 'good' control.¹¹ Furthermore, patients with diabetes with a high level of medication adherence have lower rates of hospitalisations compared with those with poor adherence, which results in significantly decreased disease-related medical costs.¹³ The potential to raise adherence levels and thus decrease healthcare and pharmacy costs is therefore a valuable proposition for those health systems looking to reduce long-term expenses.

With the passing of the Affordable Care Act (ACA), community health clinics are faced with the challenge of reducing costs without compromising quality in order to serve the largest possible number of patients. Safety net clinics still serve as significant contributors to the healthcare needs of the remaining uninsured which, though decreasing since the advent of the ACA, remains substantial and vulnerable particularly in light of political wavering on the stability of the healthcare act. Rising medication costs, a lack of value-conscious prescribing behaviour and poor medication adherence threaten the budgets of free clinics, like EHHOP, that serve the uninsured. Encouraging providers to practice value-conscious decision making has the potential to decrease pharmacy-related expenditures while preserving quality of patient care.¹⁴ In fact, a 2010 health policy literature review by Kesselheim *et al* suggests that value-based decision making by providers is a significant opportunity to eliminate unnecessarily high prescription drug costs in the USA.¹⁵ Improving patients' adherence to medications could prevent future adverse healthcare costs and overprescribing.¹⁰

In this project, we aimed to reduce pharmacy expenditures by developing interventions that promoted cost-conscious, value-based prescribing practices among providers and increased patient medication adherence through practices that capitalise on the strengths of electronic prescribing.

BASELINE MEASUREMENTS

Value-conscious prescribing of statins

To examine which prescribed medications were contributing the most to our pharmacy costs, all drug-related invoices from 2014 were reviewed in two ways: (1) medications most frequently prescribed and (2) medications that were most costly to the clinic. With regards to statins, simvastatin was the fourth most prescribed medication with 139 annual prescriptions; the sum of all simvastatin

prescriptions cost the clinic \$101.97. In contrast, rosuvastatin was prescribed only 31 times but cost the clinic \$3871.80. This difference of nearly \$4000 in cost for two lipid-lowering medications of the same class, and of similar quality, demonstrated a need to address the discrepancy in value-based prescribing.

Medication adherence to oral hypoglycaemic medications

Baseline data collection: as nearly 32% of all pharmacy costs stemmed from oral diabetes medications, we assessed baseline adherence in patients on metformin and/or glimepiride, the two most commonly prescribed oral hypoglycaemic agents at the EHHOP clinic. Two quantitative tools were employed to identify baseline measurements of medication adherence: per cent days covered (PDC) and the Morisky Medication Adherence Scale (MMAS).¹⁶ The PDC reflects a ratio of the number of days a patient has his medication supply compared with the number of days for which his medication is prescribed. For example, if a patient is prescribed three refills of a 30-day prescription and fills these prescriptions on day 1, day 32 (minus 2 days of coverage), day 62 (minus 0 days of coverage) and day 95 (minus 3 days of coverage), this person's PDC would be 0.94 (85/90). As all our prescriptions were handled through an internal pharmacy, we had the ability to track patient completion of all pharmacy refills. We used data available on the electronic medical record (EMR) to calculate a PDC for each patient for 6 months prior to October 2015.

The self-report MMAS is a questionnaire that consists of eight questions and has been validated in both English and Spanish and in adults with diabetes.¹⁷⁻¹⁹ It provides an assessment of both the extent of adherence and reasons for deviation from prescribed regimens. Possible MMAS-8 scores are high, medium and low adherence. MMAS surveys were administered between June–September 2015 for baseline data collection and were administered by clinic staff to eligible patients during their clinic appointments.

Two qualitative methods supplied the authors with baseline information on specific barriers with the potential for greatest impact. First, a qualitative questionnaire administered to patients presented open-ended questions about patients' experiences at the pharmacy. The most commonly reported reason for non-adherence on this survey was 'forgetting to pick up refills'. Several patients also described long wait times and prescriptions 'not being ready' at the pharmacy as barriers to adherence. Second, non-structured interviews with pharmacy staff revealed several more pharmacy-related barriers, the majority underlining a lack of Spanish language resources. For instance, patients needing a refill had to call the pharmacy ahead of time and leave a voicemail message with certain self-identifying information before presenting to pick up prescriptions. However, the instructions to leave a voicemail message on the employee pharmacy answering machine were only provided in English. Additionally, all directions on prescriptions sent to this

pharmacy were required to be transcribed in English. Any additional Spanish instructions on the medication directions were removed, since limited pharmacy employees were fluent in Spanish and each translation had to be verified for correctness.

Baseline data were collected from May to October of 2015. Adherence was defined as $\geq 80\%$ PDC and an MMAS score of 'medium' or 'high', which were standards used in previous adherence studies.^{20,21} Our baseline measurement of adherence included 29 patients with diabetes with an average age of 52 years, 24 of whom spoke primarily Spanish. Eighteen patients were on metformin, 1 was on glimepiride and 10 were on both. Of these patients, 45% were non-adherent, and the average PDC was 77.98%. These data indicate that while some patients were highly adherent to prescribed oral diabetes medications, a wide range of adherence behaviours exist within our patients with diabetes, with nearly half of patients demonstrating significant non-adherence.

DESIGN

Using the Institute for Healthcare Improvement (IHI) Model for Improvement, we simultaneously designed Plan-Do-Study-Act (PDSA) cycles aimed at addressing each of these contributing factors.²² Value-conscious prescribing requires that providers consider the cost and the efficacy of the medications they prescribe that that they assess if their patients are taking prescribed medications appropriately. Ensuring that patients receive the full 'value' from their prescriptions requires assessing and addressing patient adherence.

Value-conscious prescribing

The overall goal of the value-conscious prescribing interventions was to generate evidence-based prescribing resources that augment value-conscious provider education and reduce monthly average prescription costs. This involved putting a system in place to influence providers to factor cost into their decision-making process. This system used a mobile app-based decision aid. After the interventions were implemented, information regarding resulting prescription decisions were collected by reviewing the EMRs of patients who had been seen in clinic during the data collection period.

Medication adherence

To address the issue of medication adherence in our diabetic population, we investigated the factors impeding patients from filling prescriptions with regularity.

This qualitative data analysis informed us of three improvement ideas for medication adherence:

1. educate providers on auditing patient prescription refills
2. require providers to include verified Spanish language translations in prescription orders
3. implement an automated text-message reminder system to remind patients to pick-up their medication refills in a timely manner.

Data regarding medication adherence patterns were collected using the MMAS survey.

STRATEGY

Value-conscious prescribing

PDSA cycle 1

Rosuvastatin was blacklisted on the mobile-based application by including bolded text 'Do Not Prescribe' next to rosuvastatin on the mobile formulary. Student clinicians were informed of the blacklisting in the morning meeting before clinic. For five consecutive clinic days, charts of patients who were prescribed rosuvastatin were subsequently reviewed to assess if they had been switched to a more cost-effective alternative.

PDSA cycle 2

Intervention 1 demonstrated that providers were using the mobile application to make medication decisions and that changes made on formulary directly impacted pharmacy expenditures (*see Results section*). Subsequent PDSA cycles targeted the overprescribing of esomeprazole, the clinic's sixth most costly medication in 2014 at \$6 per pill. We developed a decision tree-based aid that walked providers through a series of questions about gastro-oesophageal reflux disease (GORD) symptoms and individual patient characteristics to guide the prescription of an alternative and cheaper Proton pump inhibitor (PPI) (pantoprazole at \$0.11 per tablet), antacids/H₂ blocker (\$0.02 per pill) or lifestyle modifications. We hypothesised that the decision tree aid would decrease the number of PPI prescriptions in patients where a PPI was not indicated. The decision tree aid was distributed as a fill-in via paper as a proof of concept so we could track initial uptake of our intervention and assess if it was a useful tool for our providers. Providers were asked to fill out the decision tree if they were prescribing a PPI. Over the course of five clinic days, there were 12 eligible patients who visited our clinic. The providers for five of those twelve patients used the decision tree, while the providers for the other seven did not, demonstrating a provider uptake of 42% (5/12). Of the five patients for whom the decision tree was used, four of them were switched off esomeprazole and put on H₂ blocker/antacid therapy and one was kept on antacid therapy.

PDSA cycle 3

Next, we adapted the paper decision aid onto a mobile application, in which the provider is guided through a series of questions and then given a prescription recommendation.

The use of the mobile decision application was also assessed over the course of five clinic days. Eleven patients with GORD were identified, for whom the decision tree could be applied. Clear use of the mobile-based decision tree, identified by explanation in the provider progress note, was noted in 2 of these 11 patients. One patient was switched from a esomeprazole to pantoprazole, while the other was switched from esomeprazole to no medication.

The other patients did not present an opportunity for a switch.

With clear use of the decision tree in 2 of 11 eligible patients (18% uptake), this intervention, compared with the paper format, was not significantly adequate to engage providers. As only 11 eligible patients were included in our analysis, more data are necessary to determine the uptake and utility of our decision tree aid would change with a larger sample. Factors such as having providers spend more time training with the decision tree aid may help it become better integrated into clinic flow. Further discussion with providers are needed to understand why there was such low use with this clinical indication.

Medication adherence

PDSA cycle 1

We developed EMR *text phrases*, or template short cuts, for inputting prepared Spanish phrases into orders and notes for EHHOP providers to include as additional notes in their prescription orders for oral diabetes medications. The *text phrases* contained Spanish translations of the English prescription instructions. We also developed instructions educating providers how to perform prescription refill audits on patients as an objective measure of medication adherence. Instructions for how to use our *text phrases* and perform prescription refill audits were distributed on paper to providers in clinic and were also placed on the mobile application.

PDSA cycle 2

Our initial uptake of the *text phrases* and prescription refill audits was minimal with only 4 out of 11 providers using our Spanish language *text phrases* when deemed appropriate. We implemented a clinic sign-out checklist that required providers to include Spanish language instructions in their prescriptions and perform prescription refill for all patients seen before leaving clinic for the day. We concluded that a mandatory checklist was a highly effective way to ensure our providers were mindful of how patients were adhering to their medications. Instructions on how to perform refill audits was thus incorporated into the training sessions for all new providers.

PDSA cycle 3

To address the fact that some of our patients had problems with long wait times at the pharmacy and remembering to pick up their prescription refills, we designed a text reminder to instruct patients on how to refill their prescriptions in advance. We used a system called CareMessage, which is an automated, text-based appointment reminder system that allows providers to send scheduled reminders of appointments to patients. Our reminders were sent 3 days before patients' medication supply was due to be depleted (per EMR audit) and contained instructions on how to call the pharmacy to request a timely refill. Text messages were sent in English or Spanish, depending on the patient's preferred language. These reminders were

sent only for refills of metformin and glimepiride, our formulary sulfonylurea.

PDSA cycle 4

After we sent our initial round of text reminders, we received feedback from clinic providers that some patients were reporting confusion about which prescriptions were due for refills and whether they would be receiving the text reminders for all of their medications. In early November 2015, we called all patients involved in our intervention to clarify the messaging system, obtain informed consent and verify patient understanding using a 'teach-back' method. In January 2016, we distributed a postintervention MMAS survey that included qualitative questions about patient's experiences at the pharmacy and with the automated text message reminders. We also recalculated PDC for each of the patients in our study.

RESULTS

Value-conscious prescribing

Over the course of 4 months, all 31 patients in our clinic who were on rosuvastatin were switched to atorvastatin, saving the clinic a projected \$3768 in annual pharmacy costs. This represents a 7.3% reduction in our annual pharmacy expenditures.

When the decision aids, both paper-based and mobile-based, were used, PPI prescriptions were minimised, and H2 blocker/antacid prescriptions were increased. When the decision aids was not used, no changes were made to the patient's GORD care. Provider uptake of the paper decision-making aid (PDSA 2) was 42%. Provider uptake of the mobile decision aid (PDSA 3) was 18%.

Any single switch from esomeprazole to antacid/H2 blocker, which on our formulary was ranitidine (\$0.02/pill), estimated to save \$5.98 per patient per day, amounting to an estimated yearly savings of \$2182 per patient. Any single switch from esomeprazole (\$6/pill) to pantoprazole (\$0.11/pill), assuming daily dosing, was estimated to save \$5.89 per patient per day, amounting to an estimated yearly savings of \$2149.85 per patient. Finally, a switch from esomeprazole to lifestyle modification saved \$6 per patient per day or \$2190 annually.

Overall, four patients were switched from esomeprazole to H2 blockers (PDSA 2), one patient from esomeprazole to pantoprazole (PDSA 3) and one patient from esomeprazole to lifestyle modification (PDSA3). These six switches in total therefore amounted to a total of \$13 067 saved compared with if each of these patients had remained on esomeprazole for the following year.

Medication adherence

Our postintervention measurements of medication adherence in the 29 patients with diabetes included in our study showed an increase in the number of adherent patients from 55% to 67%. The average PDC also modestly increased from 77.98% to 79.24%.

Furthermore, as of December 2015, 100% of the medications distributed to our Spanish-speaking patients,

including medications other than metformin and glimepiride, incorporated labels with prescription instructions in Spanish. This occurred following discussions with the pharmacy staff that resulted in pharmacy leadership, making it mandatory for pharmacists to include translations on all medication labels for Spanish-speaking patients.

LESSONS AND LIMITATIONS

Changing provider and patient behaviours requires multipronged approaches to make substantial and lasting impacts. Each intervention presented relative successes as well as limitations, the latter particularly related to user uptake. For example, while use of the mobile application to reduce the prescribing of restricted medications such as rosuvastatin and follow a decision tree for GORD symptom control resulted in a significant reduction in pharmacy costs, the uptake by providers was low, with clear use of the decision tree in 2 of the 11 (18%) total of patients eligible for prescription modifications. Similarly, while our automated text message reminders positively impacted adherence rates among some of our patients, medication adherence at EHHOP is likely comparable with that of other urban clinics. There are likely multiple issues that impact rates of adherence in our population from both the patient and provider perspectives. From the patient perspective, issues known to affect diabetes self-management include health literacy, financial resources, comorbidities and social support.^{23 24} From the perspective of our providers, clinician attitudes about diabetes management, provider strain due to managing multiple patients with chronic conditions and limited expertise and training on how to assess patient compliance likely affects how issues of adherence are addressed as well. Additionally, we have yet to analyse the impact on adherence of prescription instructions in Spanish on all prescriptions.

One serious limitation of our project is the absence of a long-term analysis of how our interventions will impact pharmacy expenditures moving forward. While the blacklisting of rosuvastatin had an estimated cost reduction of \$3768 over the course of a year, future analysis is necessary to confirm that the intervention has a lasting annual impact on reducing our pharmacy-related costs. Previous studies looking at the use of formularies and recommended drug lists have found a significant reduction in drug-related costs directly after the implementation of formulary restrictions.²⁵

Our analysis of medication adherence in our diabetic population did not directly consider the effect our interventions had on haemoglobin A1C rates or other markers of end-organ damage from diabetes. While our PDC measurement demonstrated that patients were picking up their medications in a timely manner, we did not measure whether patients were taking their medications at the appropriate time or at the appropriate dose.

PDC data were used as a surrogate for such measures but carries significant limitations as a true marker. A future study could look at how haemoglobin A1C values changed after our interventions were put in place as a measure of health outcomes in our patients.

Additionally, our study did not investigate the impact that improved medication adherence may have had on pharmacy-related expenditures. Due to the protracted period over which we collected our data, we did not analyse the long-term effects that adherence may have on cost-reduction in our clinic. In the future, it would be worthwhile to investigate if improved medication adherence decreased the amount of diabetic medications prescribed in our clinic and reduced overall costs.

CONCLUSION

Multipronged changes that influence provider and patient behaviours can have significant impacts on reducing pharmacy expenditures and improving patient adherence. This is particularly relevant for safety net practices that service uninsured persons who have limited means to pay out-of-pocket expenses for medications. Specifically, mobile-based tools can be used to promote value-conscious prescribing behaviour and increase medication adherence through the incorporation of decision trees, price-based formularies with restricted medications and reminder systems for patients to encourage the timely fill of medications. Training on auditing pharmacy records and checklist reminders for providers can encourage clinicians to assess medication adherence as a critical first step to controlling chronic illness before prescribing multiple or higher doses of medications. Similarly, engaging providers with a structured checklist can shift responsibility of medication adherence from the patient alone to the patient and provider as a team. Similarly, introducing a structured checklist encourages provider engagement in medication management, subsequently resulting in improved patient medication adherence. Promoting both value-conscious prescribing and improved patient adherence provides powerful constructs to mitigate the burden of rising prescription medication costs in the American healthcare system.

Contributors MYO, LC, AK, AL and JRP designed, implemented, collected data and interpreted results of the cost-reduction portion of the project. RKA, TB, FK, EL and BS designed, implemented, collected data and interpreted results of the medication compliance portion of the project. RKA and MYO wrote and edited the manuscript. RR, DT, YM and BJS oversaw the project in its entirety. All authors reviewed the manuscript.

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Data sharing statement All survey results collected through the MMAS surveys were stored on a secure computer and were only viewable by research personnel. The surveys were filled out anonymously and contained no identifiable patient data.

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